

MAY 3 0 2000

510(k) Summary of Safety and Effectiveness
K000720
Somnus Medical Technologies, Inc.
Model 1420 Disposable Tissue Coagulating Electrode
and Model RC-20 Cable

Intended Use:

The Somnus Model 1420 Disposable Tissue Coagulating Electrode and Model RC-20 Cable are intended for use with the Somnus 2-channel RF generator for the coagulation of soft tissue in the head and neck. The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Submitted by:

Somnus Medical Technologies, Inc.
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Contact Person:

Steven J. Ojala, Ph.D.
Vice President, Quality, Clinical and Regulatory Affairs
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Date Summary Prepared:

February 29, 2000

Name of the Device:

Proprietary Names: Somnus Model 1420 Disposable Tissue
Coagulating Electrode and Model RC-20 Cable

Common/Usual Name: Tissue Coagulating Electrode and Cable

Classification Name: Electrosurgical Cutting and Coagulating Device
and Accessories

Description and Predicate Devices:

The Somnus Model 1420 Disposable Tissue Coagulating Electrode and Model RC-20 Cable employ the same radiofrequency technology and basic design features as the predicate devices; Somnus Technologies' Tissue Coagulating Electrode, Model 2000 (K9961133) and the Model 1010 (K982717) and Model RC-1 Cable (K973701). It may be used in either monopolar or bipolar mode just like the predicate devices.

Accessories included with the electrode are a reusable connecting cable.

Statement of Intended Use:

The Somnus Model 1420 Disposable Tissue Coagulating Electrode and Model RC-20 Cable, in combination with a Somnus 2-channel electrosurgical generator, are indicated for the coagulation of tissue in the head and neck.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Devices:

The Somnus Model 1420 Disposable Tissue Coagulating Electrode and Model RC-20 Cable have been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance validation testing has been done to validate the performance of the device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 3 0 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Steven J. Ojala, Ph.D.
Vice President, Clinical and Regulatory Affairs
Somnus Medical Technologies, Inc.
285 North Wolfe Road
Sunnyvale, California 94086

Re: K000720
Trade Name: Somnus Model 1420 Disposable Tissue
Coagulating Electrode and Model RC-20 Cable
Regulatory Class: II
Product Code: GEI
Dated: May 8, 2000
Received: May 10, 2000

Dear Dr. Ojala:


We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Yet Assigned~~ K 000 720

Device Name: SOMNUS MODEL 1420 DISPOSABLE
TISSUE COAGULATING ELECTRODE AND
MODEL RC-20 CABLE

Indications For Use: The Somnus Model 1420 Disposable Tissue Coagulating Electrode and Model RC-20 Cable, in combination with a Somnus 2-channel electrosurgical generator, are indicated for the coagulation of tissue in the head and neck.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Contraindications for Use: The use of the Somnus Model 1420 Disposable Tissue Coagulating Electrode and Model RC-20 Cable are contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interests of the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR
(Per 21 CFR 801.109)

Over-The-Counter Use _____
(Optional Format 1-2-96)

Dan R. Vochner
(Division Sign-Off)

General Restorative Devices

510(k) Number K 000 720